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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/815,874

04/02/2004

Douglas Schein

115616

9059

25944 7590 03/09/2009  
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EXAMINER

BOWERS, NATHAN ANDREW

ART UNIT

PAPER NUMBER

1797

MAIL DATE

DELIVERY MODE

03/09/2009

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/815,874	<b>Applicant(s)</b> SCHEIN ET AL.	
	<b>Examiner</b> NATHAN A. BOWERS	<b>Art Unit</b> 1797	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 03 March 2009.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-47 is/are pending in the application.
- 4a) Of the above claim(s) 27-46 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-26 and 47 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## DETAILED ACTION

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

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1) Claims 1-3, 7-22, 26 and 47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Toledo-Pereyra (US 4186565) in view of Bacchi (US 5285657) and Cannon (US 20080032398).

With respect to claims 1-3, 7, 15, and 47, Toledo-Pereyra discloses an apparatus for holding an organ (Figure 2:K) comprising a portable housing (Figure 2:14) defining one or more openings and a tube frame (Figure 2:15) removably connectible to the portable housing. Column 1, line 51 to column 2, line 60 indicates that fluids located within the tube frame are transported to the portable housing using a system of tubes. The plurality of tubes in the tube frame are in communication with a plurality of tubes located within the portable housing in order to effectively introduce and withdrawn fluid to and from the organ. However, Toledo-Pereyra does not expressly indicate that the tubes within the tube frame are directly connected to the tubes in the portable housing, but rather depicts that the medium is moved through an external refrigerator when being transported from the tube frame to the portable housing, and through an oxygenator when being transported from the portable housing back to the tube frame.

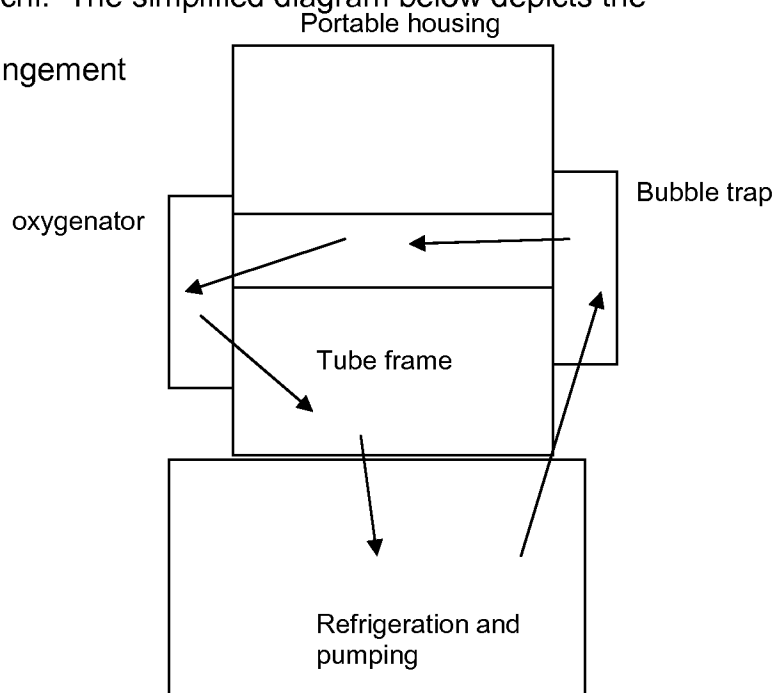
Bacchi discloses an apparatus for holding an organ or tissue during perfusion, storage, diagnosis and transport. A portable housing (Figure 2:63) provided for holding the organ is positioned within a tube frame assembly (Figure 1:10). In addition to the portable housing, a refrigeration unit (Figure 1:20) a pumping unit (Figure 1:30) and a bubble detector (Figure 1:33) are positioned inside the tube frame assembly. Fluid moving through the tubes positioned within the tube frame is moved through the refrigeration unit, pumping unit, bubble detector, and other unit operations. However,

Figure 2 clearly depicts that the tubing in the tube frame assembly is directly connected to the tubing in the portable housing via a plurality of openings (Figure 2:634 and Figure 2:631) formed on the portable housing.

Toledo-Pereyra and Bacchi are analogous art because they are from the same field of endeavor regarding tissue treatment systems.

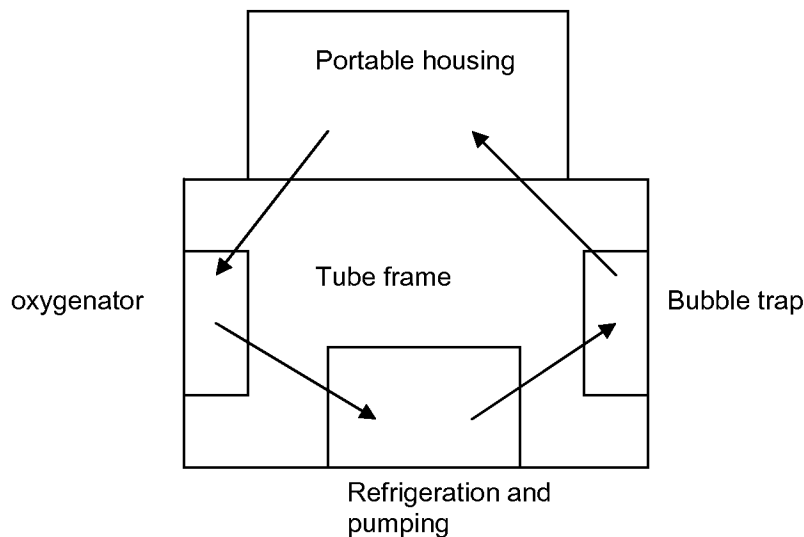
At the time of the invention, it would have been obvious to rearrange the refrigeration unit, debubbler, and oxygenator, etc to ensure that the tubing in the portable housing is directly connected to the tubing in the tube frame assembly. More specifically, it would have been obvious to one of ordinary skill in the art to move these units so that they are entirely located within the tube frame assembly, as taught by

Bacchi. The simplified diagram below depicts the arrangement



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As noted above, the tubing of the portable housing and tube frame are only indirectly connected because the tubing moves through the oxygenator, refrigeration unit and/or bubble trap. By moving the oxygenator, refrigeration unit and bubble trap inside the tube frame, as disclosed by Bacchi, the tube frame and portable housing would then be configured so as to be in direct communication.



According to this simple rearrangement of Toledo-Pereyra, the portable housing and tube frame have become directly connected. All that is required is either the enlargement of the tube frame or the reduction in size of the oxygenator, bubble trap, and refrigeration/pumping units. As evidenced by Bacchi, this arrangement is well known in the art and effective for the perfusion, transport and preservation of tissue.

Toledo-Pereyra and Bacchi, however, still differ from Applicant's claimed invention because neither reference expressly indicates that the tubes are attached to the tube frame at respective predetermined positions.

Cannon discloses a portable housing for culturing tissue cells. The portable housing includes a frame assembly (Figure 3) upon which a bioreactor is connected to fluid sources and other unit operations using a plurality of tubes (see Figure 6).

Paragraph [0062] states that the tubing is secured to the frame assembly using clips or any other fastener means capable of sufficiently securing the fluid path.

Toledo-Pereyra and Cannon are analogous art because they are from the same field of endeavor regarding tissue treatment systems.

At the time of the invention, it would have been obvious to provide the tube frame assembly of Toledo-Pereyra with clips and fasteners capable of holding each of the plurality of tubes at a desired position. This would have been a beneficial way to ensure that the flow paths do not become tangled or crushed during operation. Cannon is evidence that clips of this kind are well known in the art as effective means to organize fluid media tubes at predetermined positions within a frame assembly.

With respect to claim 8, Toledo-Pereyra, Bacchi and Cannon disclose the apparatus in claim 1 wherein a pressure sensor capable of determining fluid pressure is connectable to the tube frame. This is described by Toledo-Pereyra in column 2, lines 37-40.

With respect to claims 9 and 10, Toledo-Pereyra, Bacchi and Cannon disclose the apparatus in claim 1. Furthermore, Toledo-Pereyra discloses that a bubble trap

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(Figure 2:17) is connectable to the tube frame and in communication with tubes located in the portable housing and the tube frame.

With respect to claims 11 and 12, Toledo-Pereyra, Bacchi and Cannon disclose the apparatus in claim 1 wherein the plurality of tubes in the portable housing are connectable to an organ (Figure 2:K). Column 1, line 61 of Toledo-Pereyra states that tubes delivering fluid to the organ are connected to the organ. This is depicted in Figure 2.

With respect to claims 13, 14, 17 and 22, Toledo-Pereyra, Bacchi and Cannon disclose the apparatus in claim 1. Furthermore, Bacchi teaches in column 8, lines 1-7 that the portable housing is reversibly attached to the tube frame assembly using “a bracket or the like” (Figure 2:601). The bracket is functionally equivalent to a clip, pin or snap in that it presses the portable housing tightly against the tube frame assembly. Screws are considered to be well known means that would serve to hold the bracket in place.

With respect to claim 16, Toledo-Pereyra, Bacchi and Cannon disclose the apparatus in claim 1 wherein the portable housing and the tube frame are each supported by an organ transportation device (Figure 1:10).



With respect to claims 18-21, Toledo-Pereyra, Bacchi and Cannon disclose the apparatus in claim 17 wherein a pump (Figure 3:20) is provided for transporting fluids through the plurality of tubes found in the portable housing and the tube frame. This is disclosed by Toledo-Pereyra in column 1, lines 63-65. Toledo-Pereyra describes the use of peristaltic roller type pumps.

With respect to claim 26, Toledo-Pereyra, Bacchi and Cannon disclose the apparatus in claim 1 wherein the tube frame is made of plastic. This is described by Toledo-Pereyra in column 1, lines 54-57.

2) Claims 4 and 5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Toledo-Pereyra (US 4186565) in view of Bacchi (US 5285657) and Cannon (US 20080032398) as applied to claims 1 and 17, and further in view of Hassanein (US 6046046).

Toledo-Pereyra, Bacchi and Cannon disclose the apparatus set forth in claim 1 as set forth in the 35 U.S.C. 102 rejection above, however do not expressly state that an organ supporting surface is located within the portable housing.

Hassanein discloses a portable device for preserving organs that comprising a holding chamber (Figure 5:206) in communication with perfusion means. Hassanein teaches in column 17, lines 3-20 that a soft pad (Figure 5:218) is provided for supporting an organ or tissue within an organ bath (Figure 5:212).

Toledo-Pereyra and Hassanein are analogous art because they are from the same field of endeavor regarding organ holding apparatuses.

At the time of the invention, it would have been obvious to utilize an organ supporting surface in the apparatus of Toledo-Pereyra. Hassanein teaches that soft foam surfaces conform to the contour of the organ transported thereon, and thereby prevent bruising and physical damage. Soft foam surfaces are inexpensive and prevent lateral motion of the organ within the portable housing, and are capable of retaining an organ bath.

3) Claims 6 and 23-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Toledo-Pereyra (US 4186565) in view of Bacchi (US 5285657) and Cannon (US 20080032398) as applied to claims 1 and 17, and further in view of Fahy (US 5586438).

With respect to claim 6, Toledo-Pereyra, Bacchi and Cannon disclose the apparatus set forth in claim 1 as set forth in the 35 U.S.C. 102 rejection above, however do not expressly state that a filter is in communication with the plurality of tubes in the portable housing.

Fahy discloses the apparatus as previously described above. Fahy further indicates that a filter (Figure 1:121) is in communication with tubing adapted to supply and withdraw fluid to and from the organ. This is described in column 7, lines 15-22.

At the time of the invention, it would have been obvious to include a filter device in the perfusion system disclosed by Toledo-Pereyra. Fahy teaches that filter assemblies are beneficial because they remove undesirable particulates from fluids

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moving to the preserved organ. Fahy states that it is "very desirable to continuously filter perfusate to guard against any inadvertent introduction of microorganisms in any manner into the container."

With respect to claims 23-25, Toledo-Pereyra, Bacchi and Cannon disclose the apparatus set forth in claim 17 as set forth in the 35 U.S.C. 102 rejection above, however do not expressly state that a sensor is provided for detecting proper and improper connection between the tube frame and the organ transporter.

Fahy discloses a lid position sensor capable of detecting when the lid of the organ holding chamber is ajar. Column 13, lines 16-35 state that when the lid is determined to be in an undesirable position, the sensors will convey this information to an operator through the use of an alarm or visual display.

At the time of the invention, it would have been obvious to include a detection system capable of determining when the tube frame of Toledo-Pereyra is improperly connected to the organ transporter. This would have been beneficial because it would have prevent possible damage to the organ resulting from mechanical failures resulting from improper connections. By ensuring that each component is properly connected to the other components, one would have been able to prevent tampering with the organ or excessive heat or contaminant infiltration.

4) Claims 1-3, 7, 8, 11-15, 17-22, 26 and 47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bacchi (US 5285657) and Cannon (US 20080032398).

With respect to claims 1-3, 7, 15 and 47, Bacchi discloses an apparatus for holding an organ or tissue during perfusion, storage, diagnosis and transport. A portable housing (Figure 2:63) provided for holding the organ is removably positioned within a tube frame assembly (Figure 1:10). In addition to the portable housing, a refrigeration unit (Figure 1:20) a pumping unit (Figure 1:30) and a bubble detector (Figure 1:33) are positioned inside the tube frame assembly. Fluid moving through the tubes positioned within the tube frame is moved through the refrigeration unit, pumping unit, bubble detector, and other unit operations. Figure 2 clearly depicts that the tubing (Figure 2:66) in the tube frame assembly is directly connected to the tubing in the portable housing via a plurality of openings (Figure 2:634 and Figure 2:631) formed on the portable housing. Bacchi, however, does not expressly indicate that the tubes are attached to the tube frame at respective predetermined positions.

Cannon discloses a portable housing for culturing tissue cells. The portable housing includes a frame assembly (Figure 3) upon which a bioreactor is connected to fluid sources and other unit operations using a plurality of tubes (see Figure 6). Paragraph [0062] states that the tubing is secured to the frame assembly using clips or any other fastener means capable of sufficiently securing the fluid path.

Bacchi and Cannon are analogous art because they are from the same field of endeavor regarding tissue treatment systems.

At the time of the invention, it would have been obvious to provide the tube frame assembly of Bacchi with clips and fasteners capable of holding each of the plurality of tubes at a desired position. This would have been a beneficial way to ensure that the

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flow paths do not become tangled or crushed during operation. Cannon is evidence that clips of this kind are well known in the art as effective means to organize fluid media tubes at predetermined positions within a frame assembly.

With respect to claim 8, Bacchi and Cannon disclose the apparatus in claim 1 wherein a pressure sensor capable of determining fluid pressure is connectable to the tube frame. Bacchi discloses the use of a control unit capable of detecting and regulating fluid pressure in column 4, lines 39-55 and column 5, lines 1-2.

With respect to claims 11 and 12, Bacchi and Cannon disclose the apparatus in claim 1 wherein the plurality of tubes in the portable housing are connectible to an organ (Figure 2:O). This is depicted in Figure 2.

With respect to claims 13, 14, 17 and 22, Bacchi and Cannon disclose the apparatus in claim 1. Furthermore, Bacchi teaches in column 8, lines 1-7 that the portable housing is reversibly attached to the tube frame assembly using “a bracket or the like” (Figure 2:601). The bracket is functionally equivalent to a clip, pin or snap in that it presses the portable housing tightly against the tube frame assembly. Screws are considered to be well known means that would serve to hold the bracket in place.

With respect to claims 18-21, Bacchi and Cannon disclose the apparatus in claim 17 wherein a pump is provided for transporting fluids through the plurality of tubes found

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in the portable housing and the tube frame. Bacchi describes the use of conventional peristaltic type pumps in column 4, lines 17-26.

With respect to claim 26, Bacchi and Cannon disclose the apparatus in claim 1. Plastic is considered to be a well known material suitable for the construction of a tube frame. One of ordinary skill in the art would have been motivated to utilize plastic in the construction of the Bacchi tube frame due to its low cost and compatibility with known shaping techniques.

5) Claims 4 and 5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bacchi (US 5285657) in view of Cannon (US 20080032398) as applied to claims 1 and 17, and further in view of Hassanein (US 6046046).

Bacchi and Cannon disclose the apparatus set forth in claim 1 as set forth in the 35 U.S.C. 102 rejection above, however do not expressly state that an organ supporting surface is located within the portable housing.

Hassanein discloses a portable device for preserving organs that comprising a holding chamber (Figure 5:206) in communication with perfusion means. Hassanein teaches in column 17, lines 3-20 that a soft pad (Figure 5:218) is provided for supporting an organ or tissue within an organ bath (Figure 5:212).

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At the time of the invention, it would have been obvious to utilize an organ supporting surface in the apparatus of Bacchi. Hassanein teaches that soft foam surfaces conform to the contour of the organ transported thereon, and thereby prevent bruising and physical damage. Soft foam surfaces are inexpensive and prevent lateral motion of the organ within the portable housing, and are capable of retaining an organ bath.

6) Claims 6 and 23-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bacchi (US 5285657) in view of Cannon (US 20080032398) as applied to claims 1 and 17, and further in view of Fahy (US 5586438).

With respect to claim 6, Bacchi and Cannon disclose the apparatus set forth in claim 1 as set forth in the 35 U.S.C. 102 rejection above, however do not expressly state that a filter is in communication with the plurality of tubes in the portable housing.

Fahy discloses the apparatus as previously described above. Fahy further indicates that a filter (Figure 1:121) is in communication with tubing adapted to supply and withdraw fluid to and from the organ. This is described in column 7, lines 15-22.

Bacchi and Fahy are analogous art because they are from the same field of endeavor regarding organ holding apparatuses.

At the time of the invention, it would have been obvious to include a filter device in the perfusion system disclosed by Bacchi. Fahy teaches that filter assemblies are beneficial because they remove undesirable particulates from fluids moving to the preserved organ. Fahy states that it is "very desirable to continuously filter perfusate to

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guard against any inadvertent introduction of microorganisms in any manner into the container.”

With respect to claims 23-25, Bacchi and Cannon disclose the apparatus set forth in claim 17 as set forth in the 35 U.S.C. 102 rejection above, however do not expressly state that a sensor is provided for detecting proper and improper connection between the tube frame and the organ transporter.

Fahy discloses a lid position sensor capable of detecting when the lid of the organ holding chamber is ajar. Column 13, lines 16-35 state that when the lid is determined to be in an undesirable position, the sensors will convey this information to an operator through the use of an alarm or visual display.

At the time of the invention, it would have been obvious to include a detection system capable of determining when the tube frame of Bacchi is improperly connected to the organ transporter. This would have been beneficial because it would have prevent possible damage to the organ resulting from mechanical failures resulting from improper connections. By ensuring that each component is properly connected to the other components, one would have been able to prevent tampering with the organ or excessive heat or contaminant infiltration.

### ***Response to Arguments***

Applicant's arguments filed 03 March 2009 with respect to the 35 U.S.C. 103 rejections involving the combination of Toledo-Pereyra and Cannon have been fully



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considered and are persuasive. Therefore, these rejections have been withdrawn.

However, upon further consideration, a new ground of rejection is made in view of the combination of Toledo-Pereyra, Bacchi and Cannon and the combination of Bacchi and Cannon.

Please also consider the new rejections in view of the combination of Toledo-Pereyra, Bacchi, Cannon and Hassanein and the combination of Bacchi, Cannon and Hassanein.

### ***Conclusion***

This is a non-final rejection.

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to NATHAN A. BOWERS whose telephone number is (571)272-8613. The examiner can normally be reached on Monday-Friday 7 AM to 4 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on (571) 272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/William H. Beisner/  
Primary Examiner, Art Unit 1797

/Nathan A Bowers/  
Examiner, Art Unit 1797